Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claim 1,4-5,11,15,28,31-34,38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno et al. in view of Alsberg ("Multiscale Cluster Analysis", 1999) as cited by applicant.

Moreno et al. disclose a method and system for optically analyzing blood vessel walls, their invention comprising: receiving optical signals from the vessel walls with a detector system; resolving a spectrum of the optical signals to generate spectral data with a spectrometer and using the spectral data to analyze the vessel walls with an analyzer (see Abstract; pg. 4, paragraph [0013]; pg. 8, paragraph [0051]; pg. 10, paragraph [0072]-[0076]; pg. 12, paragraphs [0084]-[0087]). The blood vessel walls are illuminated with an optical source and generates near infrared light (pg. 4, paragraph [0013]; pg. 10, paragraph [0072], [0075]). The step of receiving the optical signals comprises detecting returning radiation to a catheter head (see Abstract; pg. 4, paragraph [0013]; pg. 8, paragraph [0051]; pg. 10, paragraph [0072]-[0076]; pg. 12, paragraphs [0084]-[0087]). Moreno et al. further disclose that the spectral data is used to determine whether the blood vessel walls are comprised of vulnerable or non-vulnerable plaque (see Abstract; pg. 4, paragraph [0013]; pg. 8, paragraph [0051]; pg. 10,

paragraph [0072]-[0076]; pg. 12, paragraphs [0084]-[0087]). They further disclose that the spectral data underwent preprocessing (pg. 10, paragraph [0075]).

However, Moreno et al. do not disclose that their method involves transforming the spectral data into dual-domain spectral data. They further do not specifically disclose that the step of transforming the spectral data into dual-domain spectral data is performed as a preprocessing step, before application of a discrimination model (i.e. single or dual domain model).

Alsberg discloses how the concept of multiresolution is used with cluster analysis of spectral data (pg. 3092, abstract). They disclose that performing cluster analysis in the time-frequency domain (i.e. dual-domain) makes it possible to obtain information that would be difficult to obtain using only the time/spectral domain (pg. 3092, right column, 2nd paragraph). To obtain information about a signal in the time-frequency domain it is necessary to construct bases that have localization in both time and frequency (i.e. transform spectral data into dual-domain spectral data). A discrimination model is applied to the transformed data (pg. 3097, right column). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Moreno to have the spectral data transformed into dual-domain spectral data, as taught by Alsberg, in order to obtain information that would be difficult to obtain using only the time/spectral domain (pg. 3092, right column, 2nd paragraph).

3. Claim 1-7,9-11,13-18,20-22,28-34,36-45,47-49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno et al. (US Pub No. 2001/0047137) in view of Tan ("Dual-domain regression analysis for spectral calibration models", February 2003) as cited by applicant.

Moreno et al. disclose a method and system for optically analyzing blood vessel walls, their invention comprising: receiving optical signals from the vessel walls with a detector system; resolving a spectrum of the optical signals to generate spectral data with a spectrometer and using the spectral data to analyze the vessel walls with an analyzer (see Abstract; pg. 4, paragraph [0013]; pg. 8, paragraph [0051]; pg. 10, paragraph [0072]-[0076]; pg. 12, paragraphs [0084]-[0087]). The blood vessel walls are illuminated with an optical source and generates near infrared light (pg. 4, paragraph [0013]; pg. 10, paragraph [0072], [0075]). The step of receiving the optical signals comprises detecting returning radiation to a catheter head (see Abstract; pg. 4, paragraph [0013]; pg. 8, paragraph [0051]; pg. 10, paragraph [0072]-[0076]; pg. 12, paragraphs [0084]-[0087]). Moreno et al. further disclose that the spectral data is used to determine whether the blood vessel walls are comprised of vulnerable or non-vulnerable plaque (see Abstract; pg. 4, paragraph [0013]; pg. 8, paragraph [0051]; pg. 10, paragraph [0072]-[0076]; pg. 12, paragraphs [0084]-[0087]). They further disclose that the spectral data underwent preprocessing (pg. 10, paragraph [0075]).

However, Moreno et al. do not disclose that their method involves transforming the spectral data into dual-domain spectral data.

Tan et al. disclose a regression model that not only emphasizes local features but also uses the less obvious information embedded over entire frequency and time domains (pg. 111, abstract, right paragraph). The dual-domain algorithms generate more parsimonious regression models that are also more robust against unexpected variations in the prediction set than single domain algorithms (pg. 111, abstract). The spectral data is transformed into dual-domain spectral data as a preprocessing step, before application of multivariate regression techniques, which comprise applying a weight strategy (i.e. cross-validation techniques) and a discrimination model (pg. 111, right column -pg. 114, section 2.2, Dual-domain regression analysis (DDRA)). The dual-domain regression analysis comprises applying a wavelet prism (pg. 112, Section 2.1 Dual-domain spectra, see Figure 1). Further, the step of transforming the spectral data into the dual-domain spectral data comprises applying a time-frequency transform and decomposition methods, optimized in response to analytes and interferants (pg. 112, Section 2.1 Dual-domain spectra). At the time of the invention, it would have been obvious to one of ordinary skill in the art to transform the spectral data into dual-domain spectral data in the method of Moreno et al, as taught by Tan et al., as dual-domain spectral analysis is more robust, has fewer latent variables and has better predictive performance (pg. 111, abstract).

4. Claims 8, 24 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno et al. in view of Tan as applied to claims 1 and 28 above, and further in view of Carr (US Pub No. 2004/0243004).

As discussed above, the above combined references meet the limitations of claim 1. However, they do not specifically disclose that the step of using dual-domain spectral data to analyze the vessel wall comprises measuring vulnerability for a risk of heart attack. Carr discloses a minimally invasive technique for detecting vulnerable plaques (pg. 1, paragraph [0001]). They disclose that coronary disease can be caused by vulnerable plaques which are engrained or embedded in the arterial wall (pg. 1, paragraphs [0003]-[0004]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have their step of analyzing the vessel walls comprise measuring vulnerability for a risk of heart attack, as Carr teaches that coronary disease can be caused by vulnerable plaques which are engrained or embedded in the arterial wall (pg. 1, paragraph [0003]-[0004]).

5. Claims 19, 23, 25, 46, 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno et al. in view of Tan et al. as applied to claims 1 and 28 above, and further in view of Braun et al. (US Patent No. 6,321,164).

As discussed above, the above combined references meet the limitations of claims 1 and 28. However, they do not specifically disclose that their analysis further comprises applying a receiver operating characteristic-area under curve analysis, and that such an analysis can be used to set a decision boundary. Braun et al. disclose a method and apparatus for predicting the presence of at least one congenital or acquired imbalance or therapeutic condition from at least one time-dependent measurement profile (column 3, lines 29-32). They disclose

a classification process that includes using an ROC curve to determine true-positive and false-positive proportions at different "decision boundaries" for the diagnostic test (column 13, lines 1-49). They disclose that the area under the curve is equivalent to an estimate of the probability that a randomly chosen positive specimen will have a more positive result than a randomly chosen negative specimen (column 13, lines 1-49). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have their analysis further comprise applying a receiver operating characteristic-area under curve analysis, and that such an analysis be used to set a decision boundary, as their invention requires a separation/classification of data and Braun et al. disclose that an ROC curve can be used to separate and classify data (column 13, lines 1-49).

6. Claims 26 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno et al. in view of Tan et al. as applied to claims 1 and 28 above, and further in view of Zelenchuk (US Patent No. 6,768,918).

As discussed above, the above combined references meet the limitations of claims 1 and 28. However, they do not specifically disclose that their analysis comprises applying a Mahalanobis classifier. Zelenchuk disclose a system and method for the discrimination of healthy and diseased tissue (lines 55-61). They disclose that this can be done by classifying or comparing normalized intensities into one or more groups, which can be done by using a Mahalanobis-based classifier which is computationally efficient (column 2, lines 1-18, lines 44-61). At the time of the invention, it would have been obvious to one of ordinary skill in the

art to modify the invention of the above combined references to have their analysis comprise applying a Mahalanobis classifier, as taught by Zelenchuk, as this is a known method of separating/classifying data and is computationally efficient (column 2, lines 1-18).

7. Claims 27 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno et al. in view of Tan et al. and Zelenchuk as applied to claims 26 and 52 above, and further in view of Braun et al.

As discussed above, the above combined references meet the limitations of claims 26 and 52. However, they do not specifically disclose that the classifier comprises applying a receiver operating characteristic-area under curve analysis technique to set decision boundary (surface) in high dimension space. Braun et al. disclose a method and apparatus for predicting the presence of at least one congenital or acquired imbalance or therapeutic condition from at least one time-dependent measurement profile (column 3, lines 29-32). They disclose a classification process that includes using an ROC curve to determine true-positive and false-positive proportions at different "decision boundaries" for the diagnostic test (column 13, lines 1-49). They disclose that the area under the curve is equivalent to an estimate of the probability that a randomly chosen positive specimen will have a more positive result than a randomly chosen negative specimen (column 13, lines 1-49). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have their classifier comprise applying a receiver operating characteristic-area under curve analysis technique to set a decision

boundary, as their invention requires a separation/classification of data and Braun et al. disclose that an ROC curve can be used to define a decision boundary (column 13, lines 1-49).

Response to Arguments

8. Applicant's arguments with respect to claims 1-53 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine L Fernandez/
Examiner, Art Unit 3768

/Eric F Winakur/
Primary Examiner, Art Unit 3768